4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1145]

Aurolife Pharma LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 072514	Clorazepate Dipotassium Tablets, 3.75 milligrams (mg), 7.5 mg, and 15 mg	Aurolife Pharma LLC, 2400 US Hwy. 130 N., Dayton NJ 08810
ANDA 077840	Ondansetron Hydrochloride Injection, Equivalent to (EQ) 2 mg base/milliliters (mL)	Hospira, Inc., 275 N. Field Dr., Bldg. H1, Lake Forest, IL 60045

Application No.	Drug	Applicant
ANDA 077988	Fluconazole in Dextrose 5% Injection, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL)	Woodward Pharma Services LLC, 47220 Cartier Dr., Wixom, MI 48393
ANDA 203265	Lidocaine Patch, 5%	Noven Pharmaceuticals, Inc., 11960 SW 144th St., Miami, FL 33186
ANDA 203967	Escitalopram Oxalate Solution, EQ 5 mg base/5 mL	Antrim Pharmaceuticals LLC, 655 W. Northcroft Ct., Lake Forest, IL 60045

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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